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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,092

05/13/2005

Thomas C Kienzle III

14131US02

1923

23446 7590 05/24/2010  
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EXAMINER

ABRAHAM, SALIEU M

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

05/24/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,092	<b>Applicant(s)</b> KIENZLE, THOMAS C	
	<b>Examiner</b> SALIEU M. ABRAHAM	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41 is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1– 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,235,038 to Hunter (**Hunter**).

#### In Reference to Claim 1

**Hunter** teaches:

A system for tracking the position of an instrument relative to an area of interest (i.e. the surgical operating area; see abstract) comprised of a single or plurality of fixators (translational devices; see fig. 1) to include first (20), second (60, 80 or 100) or more (abstract, col. 5, lines 2-15) that can be secured to various points along an area of interest (fig. 1 and col. 5, lines 16-52), the fixators all being configured to carry interchangeable first and second localizing devices (optical or electromagnetic transmitters/receivers; see col. 5, lines 52-57) and whereby a third localizing device positioned proximate a third point along the area of interest (col. 5, lines 2-15) such that *it is capable of communicating* with other localizing devices directly or indirectly such that its position relative to the other localizing device(s) is known (col. 5, lines 9-15).

#### In Reference to Claim 2

**Hunter** teaches the system of claim 1, wherein the first localizing device is an electromagnetic transmitter and the second and third localizing devices are

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electromagnetic receivers. (col. 6, lines 39-61)

In Reference to Claim 3

**Hunter** teaches the system of claim 1, wherein the first, second, and third localizing device are emitters for use in an optical tracking system. (col. 5, lines 53-58).

In Reference to Claim 4

**Hunter** teaches the system of claim 1, further comprising a computer system that monitors the communications between said first, second, and third localizing devices and calculates their relative positions. (col. 5, lines 25-26)

In Reference to Claim 5

**Hunter** teaches the system of claim 1, wherein additional localizing devices may be positioned about said area of interest. (col.5, lines 7-9)

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 6 - 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,235,038 to Hunter (**Hunter**) in view of US Pat. No. 6,827,723 to Carson (**Carson**).

In Reference to Claims 6 - 8

**Hunter** has been shown to teach all claim limitations to include image acquisition using imaging systems/modalities that commonly employ apparatus such as a C-arm

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(col. 1, lines 39-42), a fixator configured to carry an electromagnetic (EM) transmitter and receiver and fixator securement at different sites/locations as needed (e.g. a matter of design choice; see fig.1 and col. 5, lines 16-58). However, Hunter does not specifically teach a C-arm having an imaging device and fixator securement by bone screws or connectable strap to a patient.

**Carson** discloses computer-based intra-operative systems and methods for obtaining anatomical images as well as registering, navigating and tracking target anatomical sites, surgical instruments and/or implants (abstract). Carson's invention uses a C-arm with an imaging device (fig. 3) along with arthroscopic knee fixators (figs. 2-3) to which EM transceivers can be attached (14) for image registration, and surgical implement navigation and tracking (cols. 10, lines 35-67 and 11, lines 1-12). It would be obvious to one of ordinary skill in the art to employ trackable fixators as fiducials in the anatomical area being evaluated as a matter of design or study choice. It would be further obvious to one of ordinary skill that various fixator securement means could be employed in the surgical environment in order to ensure system accuracy for registration and tracking (col. ) and that screw and connectable strap securements are commonly used in the art (see Carson, col. 8, lines 10-12 and art of record < US Pat. No. 6,161,032> to Acker, see fig. 1 and col. 6, lines 53-56) as necessitated by the anatomical area under study and user choice. Lastly, it would be obvious to one of ordinary skill in the art to include C-arm apparatus and imaging device of Carson with the system of Hunter in order to facilitate intraoperative imaging as taught by Carson.

### ***Allowable Subject Matter***

5. Claim 41 is allowed.

6. The following is an examiner's statement of reasons for allowance: claim 41 is allowed because the prior art of record neither anticipates nor renders obvious the limitations of the claim with respect to setting and using localization device relative position thresholds based on a difference of any two of a plurality of device positions in order to make updated calculations of device positions and/or indicate a positional error.

***Response to Arguments/Remarks***

7. Applicant's arguments with regard to claims 1-8 and 41, filed February 25, 2010 have been fully considered, but they are not persuasive with respect to claims 1- 8. The arguments are persuasive with respect to claim 41.

8. With respect to claims 1 (dependent claims 2-3 and 5) applicant argues that the primary reference to Hunter (US 6235038) does not teach localization device (i.e. optical device as characterized by applicant; see applicant response <ARESP> pp. 17, third para., to 18 first two paras.) communication. Specifically, Hunter does not actually state that the optical elements are capable of or actually do communicate with each other (ARESP, p. 18, para. 2). Examiner asserts that Hunter discloses that the localization device(s) defined by the optical elements (and their link to an optical array, figs. 1 and 2, ref. 40) define "a working volume" that allows for a plurality of optical navigation systems to be employed in order to track medical implements (cols. 2 lines 48-67 and 3, lines 1-15 and 53-58), including surgical tools (col. 3, lines 17-18). The optical array (40) and optical element (20, 70, 85, etc.) components function as the localizing device and differ from the device of applicant in that the device does not include both position defining (element itself) and intercommunication mechanism (the array) in a single unit. However, applicant's claim as recited does not limit the localizing device to the single unit/component device embodiment. In order to establish the working volume the array and elements must necessarily be interconnected (i.e. intercommunicate) so that the volume bounds are continuously established and the position of an object within the volume can be tracked (col. 4, lines 56-65). Therefore, Hunter does disclose localization device (respective optical element and optical array) (inter)communication. The arguments for claims 4 and 6-8 are addressed as well in Examiner's argument supra (i.e. Hunter does not teach localization device communication).

9. In light of the items supra, the rejections to claims 1-8 made in the prior office action on the merits are maintained, the claim 41 rejection is withdrawn and the instant action is made non-final.

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***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bucholz et al., Grimm et al., Kormos et al., Nowacki et al., and Onik et al. have been included because they all teach the use of diagnostic imaging methods and systems which make use of electromagnetic energy for position and orientation tracking of areas of interest in vivo similar in scope to applicant's proposed invention.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 10:30 am - 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

5/21/10 SA

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768